510(k) Summary **CAAS MRV** K060941

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 19 March 2004

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS MRV software package. Pie Medical Imaging is located at:

Pie Medical Imaging BV
Becanusstraat 13 D 01
6216 BX Maastricht
The Netherlands
Phone +31.43.3281328
Fax +31.42.3281329
Email: carla.devries@pie.nl

The contact person is:	Ms. Carla de Vries, Quality Assurance Officer
The trade name is:	CAAS MRV
The common name is:	Magnetic Resonance Ventricular analysis software
The classification name is:	Image Processing System (LLZ), CFR 892.2050.

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The CAAS MRV software package is substantially equivalent to the quantitative analysis software package MRI-Magnetic resonance Analytical Software System, K994283.

The CAAS MRV is a software tool designed for the functional analysis of the heart based on multi-slice, multi-phase MR images of the heart. Therefore it provides functionality to import and view cine MR datasets of the heart from several vendors from CDROM, hard disk or (optionally) a PACS system. Next, the inner and outer wall of the ventricles can be determined either automatically, semi-automatically or manually. From these contours the ventricular volume, the ejection fraction and other related parameters are determined. Next to the quantification of the ventricular volumes, also the motion of the ventricular wall is quantified. All results of the analysis are available on screen as well as hardcopy, and can be saved.

The intended use of CAAS MRV is to enable the user to:
1. Delineate the inner and outer wall of the ventricles automatically or semi-automatically, as well as the papillary muscles, on MRI images
2. Derive from these contours the global and regional functional parameters like Ejection Fraction, Stroke Volume, Wall Movement etc.
The CAAS MRV has been designed to be used in everyday clinical practice to support clinical diagnoses, as well as for research purposes like clinical research trials.

The CAAS MRV is substantially equivalent to the predicate device mentioned in this summary by using the same technological characteristics and intended use.

The CAAS MRV is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Pie Medical Imaging B.V.
% Mr. Carl M. Beaurline
Official Correspondent
Acist Medical Systems
7450 Flying Cloud Drive
EDEN PRAIRIE MN 55344

Re: K060941
Trade/Device Name: CAAS MRV Version 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 3, 2006
Received: April 6, 2006

Dear Mr. Beaurline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Notification - CAAS MRV

INDICATION FOR USE STATEMENT

510(k) number (if known): K060941

Device Name: CAAS MRV

Indications For Use:

1. Delineate the inner and outer wall of the ventricles automatically, semi-automatically or manually, as well as the papillary muscles, on different kinds of MRI images.
2. Derive from these images and contours quantitative information to be used to assist in cardiac analysis

The CAAS MRV has been designed to be used in everyday clinical practice to support clinical diagnoses, as well as for research purposes like clinical research trials.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Feygin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060941

(Optional Format 1-2-96)